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Substitute for form 1470, 1470A, TO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 23

Complete if Known

Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1653 / 636
Examiner Name	DAVID GUZD

Attorney Docket Number 4-31890A

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (³ if known)			
JZ		US- 10/081,969	02-22-2002	Ennist, et al.	
		US- 2001/0006633A1	07-05-2001	Kirn, D.	
		US- 5,672,344	09-30-1997	Kelley, et al.	
		US- 5,677,178	10-14-1997	McCormick, F.	
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		US- 5,707,618	01-13-1998	Armentano, et al.	
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		US- 6,136,792	10-24-2000	Henderson, D.	
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		US- 6,254,862B1	07-03-2001	Little, et al.	MAY 08 2003
		US- 6,271,207B1	08-07-2001	Cristiano, et al.	RECEIVED TECH CENTER 1600/2900
		US- 6,297,219B1	10-02-2001	Nabel, et al.	
V		US- 6,432,700B1	08-13-2002	Henderson, et al.	
JZ		US- 6,436,394B1	08-20-2002	Henderson, et al.	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (³ if known)				
JZ		WO 92/03563	03-05-1992			
JZ		WO 94/18992	09-01-1994			
JZ		WO 95/19434	07-20-1995			
JZ		WO 96/34969	11-07-1996			
JZ		WO 97/01358	01-16-1997			
JZ		WO 97/04805	02-13-1997			

Examiner Signature

David Guz

Date Considered

12/18/04

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 23

Complete if Known	
Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1658
Examiner Name	DAVID GUZ
Attorney Docket Number	4-31890A

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U. S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ *-Number ⁴ -Kind Code ⁵ (if known)				
JT		WO 97/48277	12-24-1997			
JT		WO 98/13508	04-02-1998			
JT		WO 98/27207	06-25-1998			
JT		WO 98/35028	08-13-1998			
JT		WO 98/39464	09-11-1998			
JT		WO 98/39465	09-11-1998			

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Signature**

Daniel Bryan

Date Considered

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 23

Complete if Known	
Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1553
Examiner Name	DAVID GUVZ
Attorney Docket Number	4-31890

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U. S. PATENT DOCUMENTS

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J		WO 98/39466	09-11-1998			
J		WO 98/39467	09-11-1998			
J		WO 99/06576	02-11-1999			
J		WO 99/28469	06-10-1999			
J		WO 99/55831	11-04-1999			
J		WO 99/59604	11-25-1999			

Examiner Signature		Date Considered	12/18/04
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 23

Complete if Known	
Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1653 / 636
Examiner Name	DAVID GUZIO
Attorney Docket Number	4-31890

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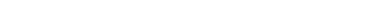
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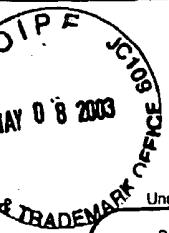
FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear T ⁶
CT		WO 00/03029	01-20-2000		
CT		WO 00/15820	03-23-2000		
CT		WO 00/22124	04-20-2000		
CT		WO 00/29599	05-25-2000		
CT		WO 00/31286	06-02-2000		
PR		WO 00/39319	06-06-2000		

Examiner Signature		Date Considered	12/18/04
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⁴EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.⁵ Applicant's unique citation designation number (optional).⁶ See Kinda Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.⁷ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).⁸ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.⁹ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.¹⁰ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 5 of 23

Complete if Known	
Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1653 / 636
Examiner Name	DAVID GUVZO
Attorney Docket Number	4-31890

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U. S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ² -Number ³ -Kind Code ⁴ (/ known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear T ⁶
JT		WO 00/46355	08-10-2000		
JT		WO 00/47768	08-17-2000		
JT		WO 00/56909	09-28-2000		
JT		WO 00/67576	11-16-2000		
JT		WO 00/70071	11-23-2000		
JT		WO 01/02540	01-11-2001		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 6 of 23

Complete if Known	
Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1658 1636
Examiner Name	DAVID GUZIO MAY 08
Attorney Docket Number	4-31890

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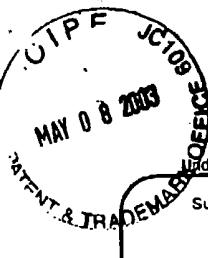
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JT		WO 01/04282	01-18-2001		
JT		WO 01/04334	01-18-2001		
JT		WO 01/23004	04-05-2001		
JT		WO 01/36650	05-25-2001		
JT		WO 01/72341	10-04-2001		
JT		WO 01/73093	10-04-2001		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 7 of 23

Complete if Known	
Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1663 / 636
Examiner Name	DAVID M UZ
Attorney Docket Number	4-31890

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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	FOREIGN PATENT DOCUMENT		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁸
		Foreign Patent Document	Publication Date MM-DD-YYYY			
SC	WO 01/83796	Country Code ² *Number ⁴ *Kind Code ⁵ (if known)	11-08-2001			
RL	WO 02/068627		09-06-2002			

Examiner Signature	Daniel Suzz	Date Considered	12/18/04
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of 23

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Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1668 / 636
Examiner Name	DAVID GUZO
Attorney Docket Number	4-31890A

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
DR		ADAMS, et al., "Transcriptional Control by E2F," Seminars in Cancer Biology, 6:99-108 (1995)	
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DR		BRISTOL, et al., "GM-CSF Containing Oncolytic Adenoviruses for the Treatment of Cancer," Abstract No. P2, presented at The 10th Annual Meeting of the European Society for Gene Therapy, Antibes, France, October 13-16, 2002	
DR		BRISTOL, et al., "GM-CSF Mediated Stimulation of Innate Anti-tumor Responses," poster presented at the Keystone Symposia, Basic Aspects of Tumor Immunology, February 17-23, 2003	

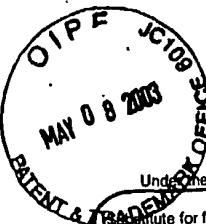
Examiner Signature	David Guzo	Date Considered	12/18/04
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INFORMATION DISCLOSURE
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Sheet

9

of

23

Complete if Known

Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1653 / 636
Examiner Name	DAVID GUZIO
Attorney Docket Number	4-31890A

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
JC		BRISTOL, et al., "GM-CSF Containing Oncolytic Adenoviruses for the Treatment of Cancer," poster presented at The 10th Annual Meeting of the European Society for Gene Therapy, Antibes, France, October 13-16, 2002	
		BRISTOL, et al., "In Vivo Anti-Tumor Activity of Oncolytic Adenoviruses that Express GM-CSF in Xenograft Tumor Models," American Society for Gene Therapy, 5th Annual Meeting, June 5-9, 2002; poster presented June 6, 2002	
		BRISTOL, et al., "In Vivo Anti-Tumor Activity of Oncolytic Adenoviruses that Express GM-CSF in Xenograft Tumor Models," Molecular Therapy, 5(5):abstract No. 311 (May 2002)	
		BRUDER, et al., "Nuclear Factor Ef-1A Binds to the Adenovirus E1A Core Enhancer Element and to Other Transcriptional Control Regions," Molecular and Cellular Biology, 9(11):5143-5153 (November 1989)	
		BRYAN, et al., "Evidence for an Alternative Mechanism for Maintaining Telomere Length in Human Tumors and Tumor-derived Cell Lines," Nature Medicine, 3(11):1271-1274 (November 1997)	
		CHANG, et al., "Immunogenetic Therapy of Human Melanoma Utilizing Autologous Tumor Cells Transduced to Secrete Granulocyte-Macrophage Colony-Stimulating Factor," Human Gene Therapy, 11:839-850 (April 10, 2000)	
		CHAO, et al., "Assembly of the Cleavage and Polyadenylation Apparatus Requires About 10 Seconds In Vivo and Is Faster for Strong Than for Weak Poly(A) Sites," Molecular and Cellular Biology, 19(8):5588-5600 (August 1999)	
		CHEN, et al., "Antiangiogenic Gene Therapy for Cancer via Systemic Administration of Adenoviral Vectors Expressing Secretable Endostatin," Human Gene Therapy, 11:1983-1996 (September 20, 2000)	
✓		CHEN, et al., "Cleavage Site Determinants in the Mammalian Polyadenylation Signal," Nucleic Acids Research, 23(14):2614-2620 (1995)	
JC		CHIA, et al., "A Novel Conditionally Oncolytic Adenovirus for the Treatment of Nasopharyngeal Carcinoma (NPC)," Proceedings of the American Association for Cancer Research, 43:1098-1099, abstract No. 5441 (March 2002)	

Examiner Signature	David Guzio	Date Considered	12/18/04
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Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1663 / 636
Examiner Name	DAVID GUZD
Attorney Docket Number	4-31890A

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<i>JR</i>		CHIOCCHA, E., "Oncolytic Viruses," Nature, 2:938-950 (December 2002)
		CHRIST, et al., "Modulation of the Inflammatory Properties and Hepatotoxicity of Recombinant Adenovirus Vectors by the Viral E4 Gene Products," Human Gene Therapy, 11:415-427 (February 10, 2000)
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		DORONIN, et al., "Tissue-Specific, Tumor-Selective, Replication-Competent Adenovirus Vector for Cancer Gene Therapy," Journal of Virology, 75(7):3314-3324 (April 2001)
<i>✓</i>		DORONIN, et al., "Tumor-Specific, Replication-Competent Adenovirus Vectors Overexpressing the Adenovirus Death Protein," Journal of Virology, 74(13):6147-6155 (July 2000)
<i>OZ</i>		DRANOFF, et al., "Vaccination with Irradiated Tumor Cells Engineered to Secrete Murine Granulocyte-Macrophage Colony-Stimulating Factor Stimulates Potent, Specific, and Long-Lasting Anti-Tumor Immunity," Proc. Natl. Acad. Sci. USA, 90:3539-3543 (April 1993)

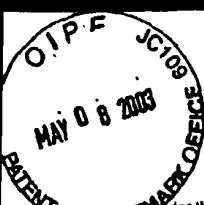
Examiner Signature	<i>David Guzdz</i>	Date Considered	12/18/04
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Sheet 11

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Complete if Known	
Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1653 / 636
Examiner Name	DAVID GUZIO
Attorney Docket Number	4-31890A

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JR		DYSON, N., "The Regulation of E2F by pRB-family Proteins," Genes and Development, 12:2245-2262 (August 1998)
		EMERY, et al., "A Chromatin Insulator Protects Retrovirus Vectors from Chromosomal Position Effects," Proc. Natl. Acad. Sci. USA, 97(16):9150-9155 (August 1, 2000)
		ENNIST, D., "Oncolytic Adenoviruses Containing GM-CSF for the Treatment of Cancer," oral presentation at the 4th International Conference, The Adjuvant Therapy of Malignant Melanoma, March 15-16, 2002
		ENNIST, D., "Oncolytic Adenoviruses Containing GM-CSF for the Treatment of Cancer," abstract presented at the 4th International Conference, The Adjuvant Therapy of Malignant Melanoma, March 15-16, 2002
		ENNIST, et al., "Oncolytic Adenoviruses Containing GM-CSF for the Treatment of Cancer," Proceedings of the American Association for Cancer Research, 43:1098, abstract No. 5437 (March 2002)
		ENNIST, et al., "Oncolytic Adenoviruses Containing GM-CSF for the Treatment of Cancer," oral presentation at the 93rd Annual Meeting of the American Association for Cancer Research, April 6-10, 2002, San Francisco, California
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		FANG, et al., "Diminishing Adenovirus Gene Expression and Viral Replication by Promoter Replacement," Journal of Virology, 71(6):4798-4803 (June 1997)
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JR		GANLY, et al., "A Phase I Study of Onyx-015, an E1B Attenuated Adenovirus, Administered Intratumorally to Patients with Recurrent Head and Neck Cancer," Clinical Cancer Research, 6:798-806 (March 2000)

Examiner Signature	<i>David Guzio</i>	Date Considered	12/18/04
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			Filing Date	February 22, 2002
			First Named Inventor	Gorziglia
			Art Unit	1653 / 636
			Examiner Name	DAVID GUZIO
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JZ		GIL, et al., "Position-Dependent Sequence Elements Downstream of AAUAAA Are Required for Efficient Rabbit -Globin mRNA 3' End Formation," Cell, 49:399-406 (May 8, 1987)	
		GOPE, et al., "Abundance and State of Phosphorylation of the Retinoblastoma Susceptibility Gene Product in Human Colon Cancer," Molecular and Cellular Biochemistry, 110:123-133 (1992)	
		GU, et al., "Tumor-Specific Transgene Expression from the Human Telomerase Reverse Transcriptase Promoter Enables Targeting of the Therapeutic Effects of the Bax Gene to Cancers," Cancer Research, 60:5359-5364 (October 1, 2000)	
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		HALLENBECK, et al., "A Novel Tumor-Specific Replication-Restricted Adenoviral Vector for Gene Therapy of Hepatocellular Carcinoma," Human Gene Therapy, 10:1721-1733 (July 1, 1999)	
		HALLENBECK, et al., "Oncolytic Adenoviruses Dependent Upon Two Prevalent Alterations in Human Cancer; Disregulation of the RB-Pathway and Telomerase," American Society of Gene Therapy 5th Annual Meeting, June 5-9, 2002, poster presented on June 5, 2002	
		HALLENBECK, et al., "Oncolytic Adenoviruses Dependent Upon Two Prevalent Alterations in Human Cancer; Disregulation of the RB-Pathway and Telomerase," Molecular Therapy, 5(5):Abstract 165 (May 2002)	
		HALLENBECK, P., "Oncolytic Adenoviruses Dependent Upon Two Prevalent Alterations in Human Cancer; Disregulation of the Rb-Pathway and Telomerase," oral presentation presented at the 3rd International Symposium on Genetic Anticancer Agents, Amsterdam, The Netherlands, March 1-2, 2002	
↓		HANS, et al., "Functionally Significant Secondary Structure of the Simian Virus 40 Late Polyadenylation Signal," Molecular and Cellular Biology, 20(8):2926-2932 (April 2000)	
JZ		HATFIELD, et al., "Redundant Elements in the Adenovirus Type 5 Inverted Terminal Repeat Promote Bidirectional Transcription In Vitro and Are Important for Virus Growth In Vivo," Virology, 184:265-276 (1991)	

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JR		HATFIELD, et al., "The NFII/OCT-1 Binding Site Stimulates Adenovirus DNA Replication In Vivo and Is Functionally Redundant with Adjacent Sequences," Journal of Virology, 67(7):3931-3939 (July 1993)	
		HAY, C., "Oncolytic Adenovirus Dependent Upon Two Prevalent Alterations in Human Cancer," The 10th Annual Meeting of the European Society of Gene Therapy, Antibes, France, October 13-16, 2002, oral presentation presented on October 16, 2002	
		HEARING, et al., "The Adenovirus Type 5 E1A Transcriptional Control Region Contains a Duplicated Enhancer Element," Cell, 33:695-703 (1983)	
		HEISE, et al., "Efficacy of a Replication-Competent Adenovirus (ONYX-015) Following Intratumoral Injection: Intratumoral Spread and Distribution Effects," Cancer Gene Therapy, 6(6):499-504 (1999)	
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		HERMISTON, T., "Gene Delivery From Replication-Selective Viruses: Arming Guided Missiles in the War Against Cancer," The Journal of Clinical Investigation, 105(9):1169-1172 (May 2000)	
		HIYAMA, et al., "Telomerase Activity in Small-Cell and Non-Small-Cell Lung Cancers," Journal of the National Cancer Institute, 87(12):895-902 (June 21, 1995)	
		HORIKAWA, et al., "Cloning and Characterization of the Promoter Region of Human Telomerase Reverse Transcriptase Gene," Cancer Research, 59:826-830 (February 15, 1999)	
↓		HURFORD, et al., "pRB and p107/p130 are Required for the Regulated Expression of Different Sets of E2F Responsive Genes," Genes & Development, 11:1447-1463 (1997)	
JR		HWANG, et al., "Polyadenylation of Vesicular Stomatitis Virus mRNA Dictates Efficient Transcription Termination at the Intercistronic Gene Junctions," Journal of Virology, 72(3):1805-1813 (March 1998)	

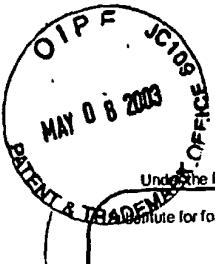
Examiner Signature	<i>David G. Zug</i>	Date Considered	12/18/04
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First Named Inventor	Gorziglia
Art Unit	1653 / 636
Examiner Name	DAVID GUZIO
Attorney Docket Number	4-31890A

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jl		International Search Report for PCT/US02/05280, February 14, 2003	
		JAFFEE, et al., "Novel Allogeneic Granulocyte-Macrophage Colony-Stimulating Factor-Secreting Tumor Vaccine for Pancreatic Cancer: A Phase I Trial of Safety and Immune Activation," Journal of Clinical Oncology, 19(1):145-156 (January 1, 2001)	
		JAKUBCZAK, et al., "Construction and Characterization of Oncolytic Adenoviruses," Molecular Therapy, 3(5):Abstract 442 (May 2001)	
		JAKUBCZAK, et al., "Construction and Characterization of Oncolytic Adenoviruses," The Fourth Annual Meeting of the American Society of Gene Therapy, May 30-June 3, 2001; poster presented on June 1, 2001	
		JAKUBCZAK, et al., "Evaluation of In Vivo Selectivity of Oncolytic Adenoviruses Following Intravenous Administration in SCID Mice Using Toxicological and Molecular Parameters," American Society of Gene Therapy, 5th Annual Meeting, June 5-9, 2002; poster presented June 7, 2002	
		JAKUBCZAK, et al., "Evaluation of In Vivo Selectivity of Oncolytic Adenoviruses Following Intravenous Administration in SCID Mice Using Toxicological and Molecular Parameters," Molecular Therapy, 5(5):abstract No. 851 (March 2002)	
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		JOHNSON, et al., "Autoregulatory Control of E2F1 Expression in Response to Positive and Negative Regulators of Cell Cycle Progression," Genes and Development, 8:1514-1525 (1994)	
↓		JOHNSON, et al., "Cytidine Deaminase-armed Selectively Replicating Adenovirus for the Treatment of Cancer," Proceedings of the American Association for Cancer Research, 43:656, abstract No. 3257 (March 2002)	
jl		JOHNSON, et al., "Selectively Replicating Adenoviruses Targeting Deregulated E2F Activity are Potent, Systemic Antitumor Agents," Cancer Cell, 1:325-337 (May 2002)	

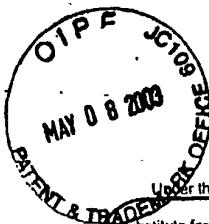
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97		KEALIN, et al., "Expression Cloning of a cDNA Encoding a Retinoblastoma-Binding Protein with E2F-like Properties," Cell, 70:351-364 (July 24, 1992)	
		KESSLER, et al., "Requirement of A-A-U-A-A-A and Adjacent Downstream Sequences for SV40 Early Polyadenylation," Nucleic Acids Research, 14(12):4939-4953 (1986)	
		KILIAN, et al., "Isolation of a Candidate Human Telomerase Catalytic Subunit Gene, Which Reveals Complex Splicing Patterns in Different Cell Types," Human Molecular Genetics, 6(12):2011-2019 (1997)	
		KIM, et al., "Specific Association of Human Telomerase Activity with Immortal Cells and Cancer," Science, 266:2011-2015 (December 23, 1994)	
		KIRN, D., "Clinical Research Results with dl1520 (Onyx-015), a Replication-selective Adenovirus for the Treatment of Cancer: What Have We Learned?" Gene Therapy, 8:89-98 (January 2001)	
		KIRN, D., "Replication-selective Microbiological Agents: Fighting Cancer With Targeted Germ Warfare," The Journal of Clinical Investigation, 105(7):837-839 (April 2000)	
		KIRN, D., "Replication-selective Oncolytic Adenoviruses: Virotherapy Aimed at Genetic Targets in Cancer," Oncogene, 19:6660-6669 (December 27, 2000)	
		KIRN, D., "Virotherapy for Cancer: Current Status, Hurdles, and Future Directions," Cancer Gene Therapy, 9:959-960 (December 2002)	
✓		KIRN, et al., "ONYX-015: Clinical Data are Encouraging," Nature Medicine, 4(12):1341-1342 (December 1998)	
✓		KIRSCHWEGER, G., "Genetic Therapies, Inc.: Tight-Lipped for Now," Molecular Therapy, 7(3):293 (March 2003)	

Examiner Signature	David Sager	Date Considered	12/18/04
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16

of

23

Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1653
Examiner Name	DAVID GUZO TECH CENTER 1600/2900

Attorney Docket Number

4-31890A

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JL		KIYONO, et al., "Both Rb/p16INK4a Inactivation and Telomerase Activity are Required to Immortalize Human Epithelial Cells," Nature, 396:84-88 (November 5, 1998)
		KOVESDI, et al., "Identification of a Cellular Transcription Factor Involved in E1A Trans-Activation," Cell, 45:219-228 (April 25, 1986)
		KURIHARA, et al., "Selectivity of a Replication-Competent Adenovirus for Human Breast Carcinoma Cells Expressing the MUC1 Antigen," The Journal of Clinical Investigation, 106(6):763-771 (September 2000)
		KWONG, et al., "Combination Therapy with Suicide and Cytokine Genes for Hepatic Metastases of Lung Cancer," Chest, 112(5):1332-1337 (November 1997)
		LA THANGUE, N., "DRTF1/E2F: An Expanding Family of Heterodimeric Transcription Factors Implicated in Cell-Cycle Control," Trends in Biochemical Science, 19:108-114 (March 1994)
		LI, et al., "A Hepatocellular Carcinoma-specific Adenovirus Variant, CV890, Eliminates Distant Human Liver Tumors in Combination with Doxorubicin," Cancer Research, 61:6428-6436 (September 1, 2001)
		LI, et al., "Replication Competent Oncolytic Adenovirus for Colon Cancer Therapy," Proceedings of the American Association for Cancer Research, 43:858, abstract No. 4251 (March 2002)
		LIMBACH, et al., "Development of Adenovirus Serotype 35 as a Gene Transfer Vector," poster presented at The 10th Annual Meeting of the European Society for Gene Therapy, Antibes, France, October 13-16, 2002
↓		LIU, et al., "Optimised Oncolytic Herpes Simplex Virus for Cancer Treatment," Abstract No. Or33, presented at The 10th Annual Meeting of the European Society for Gene Therapy, Antibes, France, October 13-16, 2002
OR		LIU, et al., "Optimized Oncolytic Herpes Simplex Virus for Cancer Treatment," poster presented at the 10th Annual Meeting of the European Society for Gene Therapy, Antibes, France, October 13-16, 2002

Examiner Signature	<i>Daniel Guzo</i>	Date Considered	12/18/04
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Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1563 / 636
Examiner Name	DAVID GUZD
Attorney Docket Number	4-31890A

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2000/2900**NON PATENT LITERATURE DOCUMENTS**

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JL		LORENCE, et al., "Systemic Therapy of Human Tumor Xenografts Using PV701, an Oncolytic Strain of Newcastle Disease Virus, in Combination with a Cytotoxic Drug Demonstrates at Least Additive Antitumor Responses," Proceedings of the American Association for Cancer Research, 43:1096, abstract No. 5428 (March 2002)	
		LYONS, R., "Multiple Approaches to Treating Systemic Disease with Oncolytic Adenoviruses," ASM Gene Therapy Conference, February 28, 2003, Banff, Alberta CA; oral presentation presented February 28, 2003	
		MABJEESSH, et al., "Gene Therapy of Prostate Cancer: Current and Future Directions," Endocrine-Related Cancer, 9:115-139 (June 2002)	
		McDEVITT, et al., "Sequences Capable of Restoring poly(A) Site Function Define Two Distinct Downstream Elements," The EMBO Journal, 5(11):2907-2913 (1986)	
		MEDINA, et al., "Adenovirus-Mediated Cytotoxicity of Chronic Lymphocytic Leukemia Cells," Blood, 94(10):3499-3508 (November 15, 1999)	
		MORRIS, et al., "Therapy of Head and Neck Squamous Cell Carcinoma with an Oncolytic Adenovirus Expressing HSV-tk," Molecular Therapy, 1(1):56-62 (January 2000)	
		NEMUNAITIS, et al., "Selective Replication and Oncolysis in p53 Mutant Tumors with ONYX-015, an E1B-55Kd Gene-Deleted Adenovirus, in Patients with Advanced Head and Neck Cancer: A Phase II Trial," Cancer Research, 60:6359-6366 (November 15, 2000)	
		NEUMAN, et al., "Structure and Partial Genomic Sequence of the Human E2F1 Gene," Gene, 173:163-169 (1996)	
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DV		OH, et al., "In Vivo and In Vitro Analyses of Myc for Differential Promoter Activities of the Human Telomerase (hTERT) Gene in Normal and Tumor Cells," Biochemical and Biophysical Research Communications, 263:361-365 (1999)	

Examiner Signature	<i>Daniel Mungo</i>	Date Considered	12/18/04
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Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1550 / 636
Examiner Name	DAVID GUVZO
Attorney Docket Number	4-31890A

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Z		PAIELLI, et al., "Evaluation of the Biodistribution, Persistence, Toxicity, and Potential of Germ-Line Transmission of a Replication-Competent Human Adenovirus Following Intraprostatic Administration in the Mouse," Molecular Therapy, 1(3):263-274 (March 2000)	
		PARDOLL, D., "Paracrine Cytokine Adjuvants in Cancer Immunotherapy," Annu. Rev. Immunol., 13:399-415 (1995)	
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		PECORA, et al., "Phase I Trial of Intravenous Administration of PV701, an Oncolytic Virus, in Patients With Advanced Solid Cancers," Journal of Clinical Oncology, 20(9):2251-2266 (May 1, 2002)	
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		POOLE, et al., "Activity, Function, and Gene Regulation of the Catalytic Subunit of Telomerase (hTERT)," Gene, 269:1-12 (May 2001)	
		POROSNICU, et al., "Increased Efficiency of the Selectively Oncolytic Vesicular Stomatitis Virus by Genetic Manipulation with Expression of Suicide Genes," Proceedings of the American Association for Cancer Research, 43:1096-1097, abstract No. 5431 (March 2002)	
		POWELL, et al., "A Conditionally Replicative Adenovirus Driven by the Human Telomerase Promoter Provides Broad-Spectrum Anti-Tumor Activity," Molecular Therapy, 5(5):abstract No. 51 (May 2002)	
↓		PRELL, et al., "Tumor Necrosis Factor -armed Defective p53-pathway Selective Replicating Adenovirus for Cancer Treatment," Proceedings of the American Association for Cancer Research, 43:1110, abstract No. 5500 (March 2002)	
DR		RAMACHANDRA, et al., "Re-engineering Adenovirus Regulatory Pathways to Enhance Oncolytic Specificity and Efficacy," Nature Biotechnology, 19:1035-1041 (November 2001)	

Examiner Signature	<i>David Guzlo</i>	Date Considered	12/18/04
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Sheet 19

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Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1663-1636
Examiner Name	DAVID GUZO

Attorney Docket Number

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DR		RASCHKE, et al., "A Replication Competent Dual-ad Vector for Treatment of Prostate Cancer," Abstract No. Or41, presented at The 10th Annual Meeting of the European Society for Gene Therapy, Antibes, France, October 13-16, 2002	
		RASSA, et al., "Molecular Basis for Naturally Occurring Elevated Readthrough Transcription Across the M-F Junction of the Paramyxovirus SV5," Virology, 247:274-286 (1998)	
		REDDY, et al., "Development of Adenovirus Serotype 35 as a Gene Transfer Vector," American Society of Gene Therapy 5th Annual Meeting, June 5-9, 2002, poster presented June 6, 2002	
		REDDY, et al., "Development of Adenovirus Serotype 35 as a Gene Transfer Vector," American Society of Gene Therapy 5th Annual Meeting, June 5-9, 2002, Molecular Therapy, 5(5):S67-S68, abstract No. 200	
		RESZKA, et al., "New Targeting System for High-efficient Delivery of Anti-neoplastic Drugs or Genes into the Angiogenetic Areas of Liver Tumors," Proceedings of the American Association for Cancer Research, 43:663, abstract No. 3289 (March 2002)	
		RIES, et al., "ONYX-015: Mechanisms of Action and Clinical Potential of a Replication-Selective Adenovirus," British Journal of Cancer, 86:5-11 (January 7, 2002)	
		RODRIGUEZ, et al., "Prostate Attenuated Replication Competent Adenovirus (ARCA) CN706: A Selective Cytotoxic for Prostate-specific Antigen-positive Prostate Cancer Cells," Cancer Research, 57:2559-2563 (July 1, 1997)	
		RUSSELL, W., "Update on Adenovirus and Its Vectors," Journal of General Virology, 81:2573-2604 (November 2000)	
DR		RYAN, et al., "An Oncolytic Adenovirus Dependent on Two Prevalent Alterations in Human Cancer: Efficacy, Tolerability, and Tumor-Selectivity Following Systemic Administration," Eleventh International Conference on Gene Therapy of Cancer, San Diego, CA, December 12-14, 2002, 10(Suppl. 1):abstract No. 036	
DR		RYAN, et al., "Anti-Tumor Efficacy and Preclinical Proof-of-Concept Following Systemic Administration of an Oncolytic Adenovirus Dependent Upon Two Prevalent Alterations in Human Cancer," Abstract No. Or34, presented at The 10th Annual Meeting of the European Society for Gene Therapy, Antibes, France, October 13-16, 2002	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Application Number	10/081,961
		Filing Date	February 22, 2002
		First Named Inventor	Gorziglia
		Art Unit	1653 / 636
		Examiner Name	DAVID GUZIO
Sheet 20	of 23	Attorney Docket Number	4-31890A

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GR		SANCHEZ-PRIETO, et al., "Lack of Correlation Between p53 Protein Level and Sensitivity to DNA-damaging Agents in Keratinocytes Carrying Adenovirus E1a Mutants," Oncogene, 11:675-682 (1995)	
		SAUTHOFF, et al., "Deletion of the Adenoviral E1b-19kD Gene Enhances Tumor Cell Killing of a Replicating Adenoviral Vector," Human Gene Therapy, 11:379-388 (February 10, 2000)	
		SAUTHOFF, et al., "p53 Expression Late in the Life Cycle of a Replication-competent Adenovirus Improves Tumor Cell Killing and Deletion of the Death Protein Improves Specificity," Proceedings of the American Association for Cancer Research, 43:1098, abstract No. 5439 (March 2002)	
		SCHWARZ, et al., "Interactions of the p107 and Rb Proteins with E2F During the Cell Proliferation Response," The EMBO Journal, 12(3):1013-1020 (1993)	
		SELLERS, et al., "A Potent Transrepression Domain in the Retinoblastoma Protein Induces a Cell Cycle Arrest When Bound to E2F Sites," Proc. Natl. Acad. Sci. USA, 92:11544-11548 (December 1995)	
		SHAY, et al., "A Survey of Telomerase Activity in Human Cancer," European Journal of Cancer, 33(5):787-791 (1997)	
		SHAY, et al., "Telomerase and Cancer," Human Molecular Genetics, 10(7):677-685 (April 2001)	
		SHI, et al., "Modulation of the Specificity and Activity of a Cellular Promoter in an Adenoviral Vector," Human Gene Therapy, 8:403-410 (March 1, 1997)	
DR		STEINWAEDER, et al., "Insulation from Viral Transcriptional Regulatory Elements Improves Inducible Transgene Expression from Adenovirus Vectors In Vitro and In Vivo," Gene Therapy, 7(7):556-567 (April 2000)	
DR		STEWART, D., "Oncolytic Adenovirus Dependent on Two Prevalent Alterations in Human Cancer," oral presentation presented at the Eleventh International Conference on Gene Therapy of Cancer, San Diego, CA, December 12-14, 2002	

Examiner Signature	<i>Daniel Guzio</i>	Date Considered	12/18/04
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Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1633 / 636
Examiner Name	OAV001 GVZ
Attorney Docket Number	4-31890A

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JR		STEWART, et al., "OAV001, an Oncolytic Adenovirus Dependent on Rb-Pathway Alterations in Human Cancer," American Society for Gene Therapy, 5th Annual Meeting, June 5-9, 2002; oral presentation presented June 7, 2002	
		STEWART, et al., "OAV001, an Oncolytic Adenovirus Dependent on Rb-Pathway Alterations in Human Cancer," Molecular Therapy, 5(5):abstract No. 53 (May 2002)	
		STEWART, et al., "Telomerase and Human Tumorigenesis," Seminars in Cancer Biology, 10:399-406 (December 2000)	
		STRAUSS, et al., "Unrestricted Cell Cycling and Cancer," Nature Medicine, 1(12):1245-1246 (December 1995)	
		TAKAHASHI, et al., "Analysis of Promoter Binding by the E2F and pRB Families In Vivo: Distinct E2F Proteins Mediate Activation and Repression," Genes & Development, 14:804-816 (April 1, 2000)	
		TAKAKURA, et al., "Cloning of Human Telomerase Catalytic Subunit (hTERT) Gene Promoter and Identification of Proximal Core Promoter Sequences Essential for Transcriptional Activation in Immortalized and Cancer Cells," Cancer Research, 59:551-557 (February 1, 1999)	
		TERHUNE, et al., "Regulation of Human Papillomavirus Type 31 Polyadenylation During the Differentiation-Dependent Life Cycle," Journal of Virology, 73(9):7185-7192 (September 1999)	
		TEVOSIAN, et al., "Expression of the E2F-1/DP-1 Transcription Factor in Murine Development," Cell Growth and Differentiation, 7:43-52 (January 1996)	
↓		TOLLEFSON, et al., "The Adenovirus Death Protein (E3-11.6K) Is Required at Very Late Stages of Infection for Efficient Cell Lysis and Release of Adenovirus from Infected Cells," Journal of Virology, 70(4):2296-2306 (April 1996)	
OZ		TSUKUDA, et al., "An E2F-responsive Replication-selective Adenovirus Targeted to the Defective Cell Cycle in Cancer Cells: Potent Antitumoral Efficacy but No Toxicity to Normal Cells," Cancer Research, 62:3438-3447 (June 15, 2002)	

Examiner Signature	<i>David Sugo</i>	Date Considered	12/18/04
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 22

of 23

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Application Number	10/081,961
Filing Date	February 22, 2002
First Named Inventor	Gorziglia
Art Unit	1633 / 636
Examiner Name	MAY 08 2003 DAVID G. YU TECH CENTER 1600/2900
Attorney Docket Number	4-31890A

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
JR		VASSAUX, et al., "Insulation of a Conditionally Expressed Transgene in an Adenoviral Vector," Gene Therapy, 6:1192-1197 (1999)	
		VILE, et al., "The Oncolytic Virotherapy Treatment Platform for Cancer: Unique Biological and Biosafety Points to Consider," Cancer Gene Therapy, 9:1062-1067 (December 2002)	
		WAELER, et al., "Experimental Gene Therapy of Hepatocellular Carcinoma: Expression of IL-12, 4-1BB and IL-2 From a Single Adenoviral Vector," Abstract No. P33, presented at The 10th Annual Meeting of the European Society for Gene Therapy, Antibes, France, October 13-16, 2002	
		WAHLE, et al., "The Mechanism of 3' Cleavage and Polyadenylation of Eukaryotic Pre-mRNA," Progress in Nucleic Acid Research and Molecular Biology, 57:41-71 (1997)	
		WEINBERG, R., "The Retinoblastoma Protein and Cell Cycle Control," Cell, 81:323-330 (May 5, 1995)	
		WEN, et al., "Effect of Viral Replication on Pharmacokinetics of OI/PEME, a Recombinant Oncolytic Adenovirus, in a Human Lung Cancer Xenograft Model," Proceedings of the American Association for Cancer Research, 43:1098, abstract No. 5440 (March 2002)	
		WOLD, et al., "Adenovirus Proteins that Subvert Host Defenses," Trends in Microbiology, 2(11):437-443 (November 1994)	
		WOLD, et al., "Immune Responses to Adenoviruses: Viral Evasion Mechanisms and Their Implications for the Clinic," Current Opinion in Immunology, 11:380-386 (1999)	
		YU, et al., "Identification of the Transcriptional Regulatory Sequences of Human Kallikrein 2 and Their Use in the Construction of Calydon Virus 764, an Attenuated Replication Competent Adenovirus for Prostate Cancer Therapy," Cancer Research, 59:1498-1504 (April 1, 1999)	
JR		YU, et al., "The Addition of Adenovirus Type 5 Region E3 Enables Calydon Virus 787 to Eliminate Distant Prostate Tumor Xenografts," Cancer Research, 59:4200-4203 (September 1, 1999)	

Examiner Signature	Daniel J. Yung	Date Considered	12/18/04
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Sheet 23

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Attorney Docket Number

4-31890A

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
Z		ZHOU, et al., "E1A Sensitizes HER2/neu-overexpressing Ewing's Sarcoma Cells to Topoisomerase II-targeting Anticancer Drugs," Cancer Research, 61:3394-3398 (April 15, 2001)	
Z		ZHU, et al., "In Vivo Spread of Oncolytic Adenoviruses in Xenograft Tumor Models," Molecular Therapy, 5(5):abstract No. 317 (May 2002)	
Z		ZSENGELLER, et al., "Adenovirus-Mediated Granulocyte-Macrophage Colony-Stimulating Factor Improves Lung Pathology of Pulmonary Alveolar Proteinosis in Granulocyte-Macrophage Colony-Stimulating Factor-Deficient Mice," Human Gene Therapy, 9:2101-2109 (September 20, 1998)	
Z		ZWICKER, et al., "Cell Cycle-regulated Transcription in Mammalian Cells," Progress in Cell Cycle Research, 1:91-99 (1995)	
Z		DONG, et al., "Angiotatin-Mediated Suppression of Cancer Metastases by Primary Neoplasms Engineered to Produce Granulocyte/Macrophage Colony-Stimulating Factor," J. Exp. Med., 188(4):755-763 (August 17, 1998)	

Examiner Signature

David Z.

Date Considered

12/18/04

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